FEB 2 5 2014

510(k) Summary

Submitter:	Nexus Spine LLC
Contact Person:	Mr. Chris Harmston, Director of Quality and Regulatory Affairs 2825 East Cottonwood Parkway Suite 330 Salt Lake City, UT 84121 Telephone: (801) 742-8342 Fax: (801) 702-8585
Date Prepared:	February 24, 2014
Trade Name:	PressON Spinal Fixation System
Classification, Name and Number:	Class II Pedicle Screw Spinal System 21 CFR 888.3070 (b) (1)
Product Code:	MNI and MNH
Predicate Device(s):	The subject device is substantially equivalent to the following devices: *OvalTwist Pedicle Screw System* Signus Medizintechnik GMBH 510(k) number K061577 *DePuy AcroMed MOSS Miami Spinal System* DePuy Acromed Inc. 510(k) number K983583 *TSRH Spinal System* Medtronic Sofamor Danek USA 510(k) number K081080 *EBI SpineLink System* EBI, L.P. 510(k) number K992920 *NuVasive SpheRx DBR II System* NuVasive, Inc 510(k) number K083028
Device Description:	The PressON Spinal Fixation System is composed of pedicle screws and rods. These components can be assembled and implanted using associated instruments via a posterior approach into the pedicles of the noncervical

	vertebral bodies. Components are made from Ti-6Al-4V ELI (ASTM F-136).
Intended Use:	The PressON Spinal Fixation System is a posterior, non-cervical pedicle screw system intended to provide immobilization and stabilization of spinal segments that can accept a device construct up to 80mm in length in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine including degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to S1) with removal of the implants after the attainment of a solid fusion.
Statement of Technological Comparison:	The PressON Spinal Fixation System is substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use and operational principles.
Performance Data:	Verification activities including static flexion-extension loading and static anterior posterior loading tests per ASTM F1798-97(2008), and static compression bending, static torsion and dynamic compression bending tests per F1717-13 indicate PressON Spinal Fixation System is substantially equivalent to predicate devices.
Conclusion:	Documentation provided demonstrates the PressON Spinal Fixation System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Nexus Spine, LLC
Mr. Chris Harmston
Director of Quality and Regulatory Affairs
2825 East Cottonwood Parkway, Suite 330
Salt Lake City, Utah 84121

Re: K133287
Trade/Device Name: PressON Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: January 27, 2014
Received: January 28, 2014

Dear Mr. Harmston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133287

Device Name
PressON Spinal Fixation System

Indications for Use *(Describe)*

The PressON Spinal Fixation System is a posterior, non-cervical pedicle screw system intended to provide immobilization and stabilization of spinal segments that can accept a device construct up to 80mm in length in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine including degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to S1) with removal of the implants after the attainment of a solid fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Colin O'Neill

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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